



ACIP Working Group on Vaccines during Pregnancy and Breastfeeding

Kathy Neuzil - ACIP Lead

Stephanie Schrag - CDC Lead

Tami Skoff - CDC

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Terms of Reference

1. **Review current recommendations on use of vaccines during pregnancy and breastfeeding**
2. **Establish guiding principles for decision-making regarding recommendations**
3. **Facilitate resolution of inconsistencies in recommendations issued by ACIP, and harmonization across professional organizations**



Workgroup Membership

- Carol Baker – ACIP
- Tracy Lieu – ACIP
- Kathy Neuzil- ACIP lead
- Doug Campos-Outcalt – AAFP
- Stanley Gall – ACOG
- Kevin Ault – ACOG
- Marion Gruber – FDA
- David Kimberlin – AAP
- Stephanie Schrag – CDC lead
- George Carlone – Tdap
- Jan Cragan – Birth defects
- Tony Fiore – Influenza
- Julianne Gee – Vaccine safety
- Diane Hoffman - Law
- John Iskander– Vaccine safety
- Megan Lindley – Evidence-based workgroup
- Lauri Markowitz – HPV
- Nancy Rosenstein Messonnier – Tdap
- Gina Mootrey – Adult schedule
- Susan Reef – Rubella
- Fran Rubin - NIH
- Judy Schmidt - CDC
- Barbara Slade – Pertussis
- Tami Skoff – CDC
- Sandy Steiner – CDC
- Susan Wang – Hepatitis B

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Laying the groundwork: review of existing recommendations

- In person meeting to introduce workgroup members, review workgroup charge, and discuss timeline for activities (Feb. '07)
- Monthly workgroup conference calls to review existing recommendations:
 - ◆ ACIP recommendations (Mar. '07)
 - ◆ FDA vaccination indications and vaccine labeling language (Apr. '07)
 - ◆ Recommendations of key professional organizations: AAP, ACOG, and AAFP (May '07)



ACIP Recommendations

(March 28th, 2007 conference call)

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ACIP: General statements on vaccines and pregnancy

- Risk to a developing fetus from vaccination of the mother during pregnancy is primarily theoretical
- No evidence exists of risk from vaccinating pregnant women with inactivated virus, bacterial vaccines or toxoids

General Recommendations on Immunization: recommendations of ACIP. MMWR 2006; 55 (RR-15)

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ACIP: Guiding Principle?

- Benefits of vaccinating pregnant women usually outweigh potential risks when the likelihood of disease exposure is high, infection would pose a risk to the mother or fetus, and vaccine is unlikely to cause harm

General Recommendations on Immunization: recommendations of ACIP. MMWR 2006; 55 (RR-15)

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Variation in ACIP Recommendations



1. Recommended for all pregnant women
 - Influenza
2. Follow routine adult immunization recommendations
 - Hepatitis B, Td, Meningococcal (MPSV4)
 - Pneumococcal (PPV23), Meningococcal (MCV4), Typhoid—*unclear if these follow routine recommendations*
3. Recommended only under special circumstances (e.g., exposure risk is high)
 - Hepatitis A, Polio (IPV), Anthrax, inactivated Japanese Encephalitis, Rabies, Smallpox, Yellow Fever, Tdap
4. Not recommended for pregnant women; unclear whether not special circumstances exist
 - LAIV, MMR, Varicella, Zoster, BCG, HPV



ACIP: General themes as viewed by workgroup



- ACIP recommendations often challenging to interpret; similar recommendations may use very different language
- Inconsistent message about the role of limited safety and/or efficacy data; data cited as a reason to recommend vaccination for some products and as a reason to avoid vaccination for others
- Majority of vaccines recommended if benefits of vaccination outweigh individual's risk; large burden placed on medical providers and pregnant women
- General statement indicating the safety of vaccination during breastfeeding

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Food and Drug Administration (FDA) Vaccine Indications (April 25th, 2007 conference call)

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FDA Pregnancy Categories

- Regulation requires that all vaccines be classified under one of five pregnancy categories (A, B, C, D, or X)
- All but two currently licensed vaccines are category C (due to lack of data)
 - ◆ HPV (category B)
 - ◆ Anthrax (category D)
- Pregnancy categories have led to confusion; FDA is in the process of revision



FDA: General themes as viewed by workgroup



- Vaccine companies write the labeling and FDA reviews; FDA does not own or author vaccine labeling
- Labeling constrained by 21 CFR 201.56; no implied claims of product use may be made if inadequate evidence of safety or lack of substantial evidence of effectiveness
- Language on vaccine labeling tends to be more conservative than ACIP recommendations
- More caution in breastfeeding statements on vaccine labeling than in ACIP statements



Recommendations of Key Professional Organizations (May 23rd, 2007 conference call)

- American Academy of Family Physicians (AAFP)
- American College of Obstetricians and Gynecologists (ACOG)
 - American Academy of Pediatrics (AAP)

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Key Professional Organizations: General Themes

- Recommendations of professional organizations are generally harmonized with ACIP; however, interpretation often varies
- Although overall harmonization exists, translation of recommendations is a major challenge; may result in altered content of recommendations
- Biggest difference in recommendations seen for Tdap; recommended for pregnant women by AAP; ACOG has not yet made a formal statement



Next Steps

- Lunch meeting on June 28th
- Begin to consider guiding principles for recommendations for vaccines during pregnancy and breastfeeding